REMARKS

Rejection of claims under 35 U.S.C. § 112

Claims 14-22 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable methods for treating multiple sclerosis. Specifically, the Office asserts that determining whether the claimed antibodies are capable of treating multiple sclerosis would require undue experimentation. The rejection is respectfully traversed.

The applicants have demonstrated that the claimed antibodies are capable of treating multiple sclerosis in an animal model. The antibodies were routinely applied to the Experimental Allergic Encephalomyelitis (EAE) model, which practitioners in the field regard as a relevant model for multiple sclerosis as made evident by Suen *et al.*, J. Exp. Med. 186: 1233 (1997) in the first paragraph of the document and in cited references 1 and 2. The Suen *et al.* document is attached herewith as Exhibit A. Because the EAE model was known as of the effective filing date of the above-captioned application and the claimed antibody was routinely applied to this model as depicted below, undue experimentation was not required to demonstrate that the claimed antibody can treat multiple sclerosis.

The claimed antibody was shown to treat multiple sclerosis as follows. First, 300 μg of MOG peptide (MEV GWY RSP FSR VVH LYR NGK) was subcutaneously co-injected with CFA (containing 500 μg of dead cells of *Mycobacterium tuberculosis*; (Becton Dicknson) to one side of the abdomen of a mouse for immunization. Simultaneously, 500 μg of pertussis toxin (ALEXIS' Biochemicals) was injected into the tail venous of the mouse. After two days from the immunization, again 500 μg of pertussis toxin was injected into the tail venous of the mouse,

and seven days later, the MOG peptide was injected for immunization into the other side of the abdomen of the mouse in the same amount as the first immunization (three mice per one group).

The scores of the conditions were the same as in the above-mentioned document. Specifically, no clinical signs received a score of 0; loss of tail tone received a score of 1; wobbly gait received a score of 2; hind limb paralysis received a score of 3; hind and fore limb paralysis received a score of 4; and death received a score of 5. Each mouse was scored, and an average for each group was calculated. The test substance MR16-1 was once intraperitonealy injected at the same time as the first immunization. A control group received PBS.

The results of the study are shown in the diagram set forth in Exhibit B. As can be seen from the diagram in Exhibit B, a single administration of the claimed antibody suppressed EAE. A declaration pursuant to 37 C.F.R. § 1.132 describing this study can be prepared and submitted if the Office requires.

Thus, the applicants have demonstrated that the claimed antibody is capable of treating multiple sclerosis in a routine study that required no undue experimentation. Accordingly, it is respectfully requested that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection of claims under 35 U.S.C. § 102

Claims 14-22 and 24-32 under 35 U.S.C. § 102(b) as allegedly being anticipated by Vink *et al.* The Office asserts that the document inherently discloses a process in which anti-IL6 receptor antibodies suppress sensitized T cells, and supports this allegation by citing *Bristol-Myers Squibb Company v. Ben Venue Laboratories*, 58 USPQ.2d 1508 (Fed. Cir. 2001) and MPEP 2112-2112.02 for the proposition that newly discovered results of known processes

directed to the same purpose are not patentable because such results are inherent. The rejection is respectfully traversed.

The facts considered in *Bristol-Myers Squibb Company v. Ben Venue Laboratories* are entirely different than those at issue in the present application. In *Bristol-Myers Squibb Company v. Ben Venue Laboratories*, the Court of Appeals for the Federal Circuit held that newly discovered results of known processes directed to the same purpose are not patentable where the patent and prior art disclosed a method for decreasing toxicity in patients undergoing paclitaxel treatment by administering the drug for only three hours instead of the twenty-four hour administration previously practiced. Thus, the court most likely arrived at this decision because the prior art and the patent dislcosures were directed to the same treatment and the same purpose for that treatment.

The close relationship between the claims and the prior art in *Bristol-Myers Squibb Company v. Ben Venue Laboratories* contrasts with the set of facts here, because Vink is directed to an entirely different purpose than that of the claims. The Vink document discusses a method for administering anti-IL6 receptor antibodies but it is directed to methods for reducing plasmacytoma, which is a disease of plasma cells, i.e., B cells. In contrast, the claimed invention is directed to the treatment of sensitized T cell-related diseases. Thus, the inherency rejection is inapplicable because the claimed subject matter is directed to an entirely different purpose (desensitizing T cells) as compared to the methods described in Vink (shrinking B cell tumors).

Furthermore, Vink provides no basis for the proposition that transfected plasmacytoma cells are accompanied by sensitized T cells. In addition, Vink provides no basis for an assertion that a substance which acts on B cells also acts on T cells. As the record provides no evidence for linking B cell modification with T cell desensitization, there is no solid ground for making

the inherency rejection because desensitizing T cells does not necessarily flow from modifying B cells. The Examiner is invited to provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2) if such information is within the Examiner's personal knowledge.

Thus, the claimed subject matter does not necessarily flow from the disclosure of Vink, because the claimed subject matter is directed to an entirely different purpose than disclosed in the document and there is no evidence that modulating B cell tumor size affects T cell sensitization. Accordingly, the claimed subject matter is not anticipated by Vink and it is respectfully requested that the rejection under 35 U.S.C. § 102 be withdrawn.

Conclusions

The applicants have overcome the rejection under 35 U.S.C. § 112, first paragraph, because they have demonstrated in a routine study that the claimed antibodies are useful for treating multiple sclerosis. Furthermore, Vink does not anticipate the claimed invention because the document is directed towards the reduction of B cell tumors, not the suppression of sensitized T cells. Accordingly, all of the rejections in the Office Action have been addressed and it is respectfully submitted that the claims are allowable.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. 350292000800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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